FINAL REPORT
GOVERNOR'S TASK FORCE
ON HOSPITAL REGULATIONS

STATE OF MARYLAND

Governor Harry Hughes
Gordon H. Dalsemer, Chairman
January, 1983

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ACKNOWLEDGEMENTS

The people involved in the preparation of this report can only be described as a most unusual group. Their names are listed in the exhibits at the back. Almost all of them were intimately involved in the work of the Task Force, and this makes any special kind of recognition extremely difficult.

Fred Gloth, Vice President and General Counsel for Blue Cross of Maryland, Inc., has been a mainstay since formation of the Task Force and the only Chairman of Track II. Working closely with Fred Gloth and the actual innovator of Track II is William Blalock, Assistant Vice President of Johns Hopkins Hospital, who has helped us keep the long term, big picture, in front of us.

The subcommittee chairmen who have made major contributions to our success are David Christman, Administrator of South Baltimore General Hospital, Elmer Horsey, Mayor of Chestertown, and Dr. Arthur Kaufman, Director of Quality Assurance for the Prince George's General Hospital.

I want to pay a special tribute to the ad hoc members, consultants and staff people who really did the work for the Task Force and who never let us down. Quite to the contrary, they usually provided the leadership.

Harold Gordon, Division of Licensing and Certification, DHMH
Larry Lawrence, Maryland Hospital Asssociation
Randall Lutz, Department of Health and Mental Hygiene
Beverly Miller, Maryland Hospital Association
Steve Summer, Maryland Hospital Association
Renee Walter, Office of the Deputy Secretary, DHMH

I would be remiss if I did not mention, Elizabeth O'Connell, formerly Vice President for Nursing at St. Joseph's Hospital and Diane Gustafson, formerly Assistant Director of Baltimore City Hospitals, who were the initial chairpersons that led to formation of Track I. Their outstanding work for the Task Force was, unfortunately, interrupted when both of them left Baltimore for more responsible posts. They were succeeded as chairperson by Dr. Arthur Kaufman, Director of Quality Assurance for the Prince George's General Hospital, who has made major contributions to both Track I and Track II.

Two names have been left for last. John L. Green, Deputy Secretary for Operations, Department of Health and Mental Hygiene, and Joseph R. Noll, Director of Regulatory Services, Department of Health and Mental Hygiene. These two men are basically responsible for making a success of the Task Force. Their leadership, guidance and enthusiastic support kept us striving for the best.

For many of us associated with the Task Force, this was our first intimate experience with a government agency. Most of the ordinary citizens' preconceived ideas about the operation of bureaucracies had to be tossed out of the window as we learned to esteem the people at the Department of Health and Mental Hygiene. Starting with Secretary Charles Buck, and including every single department head, staff person and secretary, we found nothing but cooperation, very hard work and most of all, creativity and leadership that was almost always above and beyond anything we had anticipated. The same laudatory comments apply to the Maryland Hospital Association and Blue Cross/Blue Shield, who backed us all the way.

It has been an experience that was sometimes discouraging but always interesting and full of enthusiasm. We are certain that none of the Task Force members would have foregone the trauma and pleasures of the last two years.

Gordon Dalsemer
Chairman

EXECUTIVE SUMMARY

The Governor's Task Force on Hospital Regulations was formed to examine the issue of excessive and duplicative regulation of hospitals. The Task Force was appointed in December of 1979 by Governor Harry Hughes and Charles R. Buck, Jr., Sc.D., Secretary of the Department of Health and Mental Hygiene.

An in-depth investigation of the rules and regulations governing the hospital industry was conducted. The Task Force found numerous instances of duplication, particularly in the area of inspection/licensure and certification of hospitals. Massive overlap and duplication was not documented, however. A broad set of recommendations designed to eliminate the duplication identified by the Task Force was developed and implemented. The most far reaching recommendation put forth by the Task Force and implemented by the State resulted in the elimination of annual inspections by the State for the purpose of licensure. Legislation which authorizes the Secretary of the Department of Health and Mental Hygiene to recognize The Joint Commission on Accreditation of Hospitals accreditation for the purpose of state licensure was drafted by the Task Force and sponsored by the Governor. This legislation (HB 1621) was overwhelmingly passed by the Maryland General Assembly and signed into law on May 4, 1982.

Recommendations were also developed and implemented in the area of fire and safety inspections, inpatient psychiatric inspections, Occupational Safety and Health Administration inspections, drug control, hospital laboratories and blood bank inspections. As a result of these recommendations, inspection and compliance activities in Maryland hospitals have been significantly streamlined and consolidated.

It is estimated that approximately one to two million dollars annually will be saved by Maryland's hospitals. The Department of Health and Mental Hygiene will realize approximately $115,000 annually in savings which will be available for use in underfunded areas within the State's Division of Licensing and Certification.

The Task Force also devoted considerable time and effort to investigating the feasibility of developing a system whereby only one regulatory agency would have responsibility for any given area of concern. Three areas were studied: 1) quality of care; 2) utilization review; and 3) equal access. Recommendations were made in each of these areas.

In the quality of care area, duplication in regulatory oversight was not found. The Task Force did endorse the development of a set of guidelines to be used to formulate a systematic approach to evaluate the privileging and reprivileging of physicians and other hospital professional members. It also urged that a uniform privileging format be developed in cooperation with the various medical/hospital organizations throughout the state.

The Task Force suggests that the potential exists for the proliferation of disparate utilization review systems throughout the state. A coordinated approach to utilization review is urged, as is the conduct of a joint study by the Department of Health and Mental Hygiene, the Maryland Hospital Association, and the Medical and Chirurgical Faculty to fully examine the issue.

Extensive overlap was not found in the area of equal access for minorities. To eliminate the overlap identified, the Task Force recommended that the Federal Office on Civil Rights (OCR) assign the Department of Health and Mental Hygiene total responsibility for Title VI compliance inspections. If this is not feasible, the Department is urged to conduct joint inspections with OCR.

1.0 INTRODUCTION

The development of regulatory programs has expanded significantly since the passage of Medicare and Medicaid in 1965. As regulatory programs have grown so has the feeling that regulation, designed to solve problems and protect the public, has developed to become a problem in and of itself. Regulatory authority is thought to be fragmented among too many Federal and State agencies. Jurisdictions are said to overlap and reporting requirements are perceived as costly and onerous burdens.[1]

The Governor's Task Force on Hospital Regulations was established in December, 1979. The charge of the Task Force was to conduct a thorough examination of the rules and regulations governing the hospital industry as well as identification of the various agencies assigned regulatory authority over hospitals. The Task Force was to develop a set of recommendations designed to eliminate fragmentation in regulatory authority and duplication and overlap in rules and reporting requirements.

This report constitutes the final report of the Governor's Task Force on Hospital Regulations. It contains the background and history leading to the establishment of the Task Force, the approach used by the Task Force to carry out its charge, the problems identified, the recommendations proposed and those implemented. While the work of the Task Force is complete, there are a number of recommendations that require follow-up and additional efforts. It is the sincere hope of the Task Force that its efforts in these areas will be carried on by the appropriate parties.

1.1 Background and History

The Governor's Task Force on Hospital Regulations, established to study excessive and duplicative regulation of hospitals, was appointed by Governor Harry Hughes and Secretary of Health and Mental Hygiene, Charles R. Buck, Jr., Sc.D.

An important catalyst in the formation of the Task Force was the publication, in December of 1978, of a study entitled The Duplication of Regulation. This study, conducted by the Maryland Hospital Association, though limited in its sampling of institutions, identified numerous areas of duplication in regulatory oversight of hospitals. As a result of the concern felt by the members of the Legislature, two bills, House Joint Resolution 40 and Senate Joint Resolution 37, were passed by the General Assembly in 1979. Both resolutions called for the creation of a Governor's Task Force to address the problem identified in The Duplication of Regulation.

After consultation with the Governor, the two resolutions were assigned, by the Legislative Policy Committee, to the House of Delegates Environmental Matters Committee. Secretary Buck assigned Joseph R. Noll, Director of Regulatory Services, to work with both the Committee and the Maryland Hospital Association to explore ways of reducing duplication in hospital regulations.

[1] Maryland Hospital Association. Duplication of Regulation. December, 1978.

Following a summer of intensive study, Secretary Buck, members of the Department of Health and Mental Hygiene, Delegate Torrey Brown, Chairman, House Environmental Matters Committee, and Richard Davidson, President of the Maryland Hospital Association, met to discuss the findings of this ad hoc group. Based on the results of this meeting, Secretary Buck recommended that a Task Force on Hospital Regulations be appointed and that the purpose of the Task Force should be to examine regulatory compliance activities such as surveys, inspections, visits, and formal and informal reports which impact on health facilities and provider enterprises with the objective of:

a) eliminating, consolidating, and otherwise reducing such activities;

b) initiating revisions to applicable regulations as necessary;

c) recommending new or revised legislation as appropriate; and

d) directing initial efforts toward general hospitals, but involving other health facilities, such as nursing homes, whenever appropriate.

The following initial Task Force strategies were recommended:

a) Determine the regulatory subject areas most troublesome and costly to the hospitals.

b) Identify those areas where there is a reasonable chance of resolution.

c) Suggest legislative initiatives or revised regulations as the study progresses.

d) Disseminate information intended to improve the processes of legislative and regulatory development.

In view of the complexity of the subject matter, this Task Force was viewed as one having extended duration with replacements, additions, and other personnel changes as necessary. Staff assistance was to be provided by the Department of Health and Mental Hygiene, Blue Cross/Blue Shield, and the Maryland Hospital Association.

On October 1, 1979, Secretary Buck appointed John L. Green as Assistant Secretary for Health Regulation and Policy Analysis. One of the priority projects which Mr. Green took under his direct supervision was the Task Force on Hospital Regulations. Members of Mr. Green's administration also served as staff to the Task Force. Under the most recent Department reorganization, Mr. Green, Deputy Secretary, continued to oversee the progress of the Task Force on Hospital Regulations.

2.0 Composition of Task Force

An important aspect of the Task Force on Hospital Regulations was its broad representation. The Governor, members of the House Environmental Matters Committee, and Secretary Buck worked together to develop criteria for appointments to a 15 member Task Force, which ensured that a representative group would be assembled. Task Force members included representatives from the Maryland Hospital Association, Maryland Nurses Association, Medical and Chirurgical Faculty, Blue Cross/Blue Shield, DHMH, the general public and the General Assembly.[1]

[1]The Chairman was selected from the General Public appointees.

Mr. Gordon H. Dalsemer, Chairman of the Board of Dalsemer, Catzen and Associates, Inc., and former president of the Board of Sinai Hospital, served as Chairman. Mr. Dalsemer, and members of the Task Force were assisted by Ad Hoc appointments, which were designed to provide expertise in specific areas, and staff from the Department of Health and Mental Hygiene, Blue Cross/Blue Shield, and the Maryland Hospital Association. Members of the Task Force are listed in Exhibit I, Appendix A. Exhibit II of this Appendix lists ad hoc members, consultants and staff. Exhibit III lists subcommittees and membership in each subcommittee.

3.0 Approach Used by Task Force

The Task Force focused its efforts along two tracks. The first track focused on the identification of specific regulations which resulted in duplication, conflict, and in some cases, perceived overregulation. Commonly referred to as Track I, efforts in this area concentrated on resolving immediate problems through the development of proposals to reduce regulatory duplication.

Track I efforts were designed to resolve problems in the short term, that is, immediate resolutions were feasible. Track II efforts focused on the development of long term solutions to problems with the regulatory system. Task Force members believed that a long term strategy was needed to develop a regulatory system which would insure that only one regulatory agency would have responsibility for any given area of public concern. Both the acceptance of this approach and the feasibility of the approach were explored by the Task Force.

Track I and Track II were undertaken simultaneously. However, the Task Force spent its initial efforts on Track I. Although Track I actions and recommendations are presented first, it should be noted that many of Track II activities were also ongoing at the same time.

3.1 Track I

3.1.2 Activities

Track I was organized into two phases. Phase I focused on obtaining information on regulatory compliance activities in hospitals. Phase II entailed analysis and development of recommendations. The following mechanisms were used to gather information:

- hospital questionnaires;
- letters to hospital chief executive officers to solicit examples of regulatory duplication;
- interviews with representatives of state regulatory agencies;
- letters to consultants, lawyers and architects knowledgeable in hospital regulations;
- regulatory log sheets used by all Maryland Hospital Association member institutions to track examples of duplication in regulatory oversight; and
- meetings with hospital personnel knowledgeable in a specific area of regulation.

In addition to the above methods of obtaining information, a formidable and detailed analysis of all statutes, rules, regulations, directives, and guidelines at the federal, state, and local levels was conducted.

3.1.3 Findings and Recommendations

Contrary to the initial perceptions of the Task Force, an analysis of the information collected did not reveal massive overlap, duplication and repetition. The analysis did identify a number of important areas in which improvements could be made. The area in which duplication was found to be most prevalent was in the rules and regulations governing inspection, licensure, certification and fire safety in hospitals. The problems identified in each of the areas where duplication was found and the recommendations of the Task Force are listed in Table I.

As can be seen in Table I, each of the nine (9) recommendations put forth by the Task Force has been implemented. All but two of the recommendations were handled through the development of a memorandum of understanding among agencies within the State. A division reorganization was required to implement recommendation number 3. Legislation was required to implement recommendation number 1, which suggested that all hospital licensing authority should be placed within the Joint Commission on Accreditation of Hospitals (JCAH) accreditation process and that hospitals that are JCAH accredited should be waived from State licensing inspection.

Each of the problems identified in Track I and the recommendations developed by the Task Force are described below.

State Licensure Inspections

The most significant area in which duplication was identified was in the annual licensure inspections conducted by the State. The Joint Commission on Accreditation of Hospitals (JCAH) conducted biennial accreditation surveys for hospitals. By law, the Division of Licensing and Certification (L&C) also performed annual inspections, regardless of the type of accreditation received by an institution. Thus, every other year hospitals were surveyed by both the JCAH and the State. The State had previously moved to reduce duplication in this area by consolidating the two surveys into a combined JCAH/State survey. However, the State still inspected hospitals that received a two-year accreditation during the alternate year. In spite of previous efforts to consolidate, the Task Force concluded that the existing arrangement still resulted in a duplication of effort. For instance, the same area of the hospital was often inspected separately by different inspectors, each of whom looked at the same records and procedures.

In order to resolve this duplicative arrangement, the Task Force recommended that the State (Division of Licensing and Certification) withdraw from inspection of acute general hospitals and private psychiatric hospitals and delegate inspection responsibility to the JCAH. Under this arrangement, hospitals holding JCAH accreditation would automatically be "entitled" to a state license.[1]

Implementation of this recommendation required the development of legislation authorizing the Secretary of Health and Mental Hygiene to delegate inspection authority to the JCAH. The Task Force formed a subcommittee to develop a legislative proposal for its consideration.

The major objective of the legislation drafted by the subcommittee was to create a system whereby JCAH accredited hospitals would not be surveyed by the State for the purpose of State licensure. Those hospitals holding JCAH accreditation would

[1] Currently all acute care general hospitals are JCAH accredited

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automatically be entitled to a State license for the term of their accreditation. Thus, a hospital fully accredited by JCAH for three years would be issued a license good for three years.

The legislation also gave the Division of Licensing and Certification authority to inspect hospitals that are not JCAH accredited. Inspections in non-JCAH hospitals would be conducted in all areas pertaining to patient care and safety, including medical and nursing supervision, physical environment, sanitation, dietary, and fire and safety.

A process to address complaints filed against hospitals was also outlined in the legislation. The process was designed to give hospitals the opportunity to correct problems before the State became involved. Those complaints not considered life-threatening were to be referred directly to the hospital. Issues relating to the practice of medicine or the licensure or conduct of health professionals were to be referred first to the hospital and, as appropriate, to the responsible licensure board for resolution. In those instances where the Department determined that a hospital had not satisfactorily addressed a complaint, or where the complaint alleged the existence of a life-threatening deficiency, the Department was authorized to conduct an independent investigation. The Department, in conducting its investigation, would be required to use JCAH standards for JCAH accredited hospitals.

The full Task Force endorsed the draft legislation developed by the Subcommittee. The legislation was forwarded to the Secretary of Health and Mental Hygiene who accepted the proposal and recommended that it be included in the Governor's 1982 legislative package. The Governor accepted this recommendation. Task Force members actively participated in lobbying for the bill (HB 1621) which was overwhelmingly passed by both the House and Senate. The bill was signed into law on May 4, 1982, and became effective on July 1, 1982.

The elimination of the annual state inspection resolved the most significant problem of duplication found by the Task Force. Although the elimination of annual state licensure inspections was the most far reaching of the recommendations proposed by the Task Force, there were, also, other proposals to resolve problem areas. Each is discussed below.

Inpatient Psychiatric Licensure Inspections

The Mental Hygiene Administration required that psychiatric units of general hospitals receive a separate and distinct license for their psychiatric beds. This was to be accomplished by conducting two inspections each year by the Mental Hygiene Administration. These six month inspections were considered redundant and unnecessary given that Licensing and Certification licensed these facilities annually. The Mental Hygiene Administration's efforts were viewed as redundant and the Task Force recommended that the Division of Licensing and Certification be assigned this responsibility. With the passage of HB 1621, this responsibility has now been transferred to the JCAH. The JCAH has agreed to work with the Mental Hygiene Administration to develop a separate protocol that is specific to Maryland, that is, it will be tailored to meet requirements specified in Maryland State Law.

Inspection of Hospital Laboratories

Numerous agencies have historically been involved in the inspection of hospital laboratories. The Task Force found that both the Laboratory Administration of the Department of Health and Mental Hygiene and the College of American Pathologists conducted inspections of hospital laboratories. These inspections were not coordinated. After an investigation of the purpose of each of the inspections, and the frequency and nature of follow-up activities required, the Task Force determined that separate inspections were unnecessary and duplicative. It was, therefore, recommended that the Laboratory Administration accept approvals granted by the College of American Pathologists. A directive was issued by Charles R. Buck, Jr., Secretary of Health and Mental Hygiene, to the Director of the Laboratory Administration requesting that he implement the recommendation of the Task Force by July 1, 1982.

Inspection of Blood Banks

The same problem identified in the inspection of hospital laboratories was identified in the inspection of blood banks. The Task Force could not find any justification for separate inspections to be conducted by the Laboratory Administration. Therefore, the Task Force recommended that the Department accept the inspections conducted by the American Association of Blood Banks. A directive from Charles R. Buck, Jr., Secretary, DHMH, to the Director of the Laboratory Administration accomplished this recommendation.

Drug Control Inspections

Acute general hospital pharmacies have historically been inspected by the Division of Licensing and Certification as well as the Division of Drug Control. Upon investigation of the purpose and scope of each investigation, the Task Force concluded that inspections should be carried out solely by the Division of Drug Control. It was further recommended that more comprehensive regulations should be promulgated by the Board of Pharmacy. This change would intensify the level and depth of the surveys, assign responsibility to one organization, and expand the scope to include the sub-drug units at nursing stations or other satellite drug dispensing areas of the hospital. This recommendation has been implemented through a reorganization of the Divison of Drug Control.

Occupational Safety and Health Inspections

Occupational Safety and Health inspections are another area in which the Task Force found duplicative survey practices. Traditionally, inspections have been conducted by the Office of the Commissioner of Labor and Industry, Department of Licensing and Regulation. Inspections were also frequently carried out by the Divison of Licensing and Certification. Again, the Task Force recommended coordination of inspections under one agency and suggested that the responsibility be reassigned to DHMH, Title VI. This recommendation was also accepted and has been implemented through a memorandum of understanding.

Fire Safety Inspections

Life safety inspections in hospitals are carried out by local fire authorities, the State Fire Marshal and the Joint Commission on Accreditation of Hospitals. Inspections are not coordinated and requirements may differ. The Task Force found that the potential exists for differences in opinion among state, local and JCAH inspectors. In order to minimize the existence of such misunderstandings, to the extent possible, the

Task Force recommended that joint inspections be conducted by the JCAH and state and local officials. The JCAH should also accept local recommendations when local authorities are participating in an inspection.

The Baltimore City Fire Department has agreed to coordinate its inspections with the JCAH. It is also expected that the State Fire Marshal will coordinate his inspections with the JCAH.

Several additional problem areas were identified during the course of Track I activities which Task Force members felt required further examination. These areas included: building and life safety codes and formulation of regulations. Committees were assigned to investigate each of these areas and develop recommendations to resolve any problems found. Findings and the recommendations are briefly discussed below.

Building and Life Safety Codes

The Task Force found that hospitals, depending upon their geographic location, must comply with several building and safety codes such as; Maryland State Code; Washington Suburban Sanitary Commission; National Building Code, American Insurance Association; Basic Building Code, Building Officials and Code Administrators; Standard Building Code, Southern Building Code Congress; National Conference of States on Building Codes and Standards; and National Electric Code, National Fire Protection Association. Inspectors from different agencies use different codes as the standard against which the institution's performance is measured. The Task Force found not only the use of various codes but inconsistencies and conflicting requirements among the various codes and different interpretations of the codes.

A Subcommittee comprised of hospital architects, representatives from the State Fire Marshal's Office, the Department of Health and Mental Hygiene, the Maryland Hospital Association, and knowledgeable electrical and mechanical engineers was appointed. After several meetings and thorough discussion, they found that the many complications inherent in the consolidation of codes would make it extremely difficult to obtain the cooperation of all counties and Baltimore City in this area. The committee concluded that the feasibility of persuading these groups to use standard criteria and standards was very small. Feasibility was limited because of the practicality of the consolidation and the cost associated with such an effort. Although the Task Force decided not to pursue this area further, it firmly believes that the standardization of codes for health care institutions specifically should be a long term goal of public and private agencies in the industry. It is strongly recommended that this issue be continually evaluated by hospitals, the Department of Health and Mental Hygiene, and health care professionals.

Formulation of Regulations

In accordance with state law, all proposed new regulations must be published in the Maryland Register. The text of these regulations must comply with the organization and format specified by the Division of State Documents. When filing a proposed regulation, the promulgating agency must provide specific information for publication in the Maryland Register. One of the required components is an economic impact statement. Many regulations require the collection and reporting of data, which also has an inherent dollar value. However, this cost of compliance is not contained in the economic impact statement.

The Task Force suggested that in the interest of assessing the cost of complying with regulations, the promulgating agency should provide a statement of the data requirements associated with all proposed regulations. This statement should delineate the specific type of information and/or reports necessary to comply with the new regulation. The frequency of collecting and/or reporting the data should also be included. In addition, the estimated dollar value of the data collection, aggregation, and distribution should be indicated.

In order to accomplish this, it was recommended that the Department of Health and Mental Hygiene modify Administrative Order Number One to require the inclusion of a data impact statement in all newly promulgated regulations.[1] Action has been taken by the Department to implement this recommendation.

A second and related problem concerns the complexity of regulations promulgated by state agencies. Regulations are often confusing to read and difficult to comprehend. In the interest of streamlining the regulatory process and reducing unnecessary ambiguity and complexity, the Task Force believes that regulations should be written as clearly and precisely as possible. To that end, the Task Force has compiled a list of state and federal sources available to assist in drafting regulations. This list may be found in Appendix B.

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[1]Administrative Order Number One is the DHMH procedure which identifies the steps necessary for rules and regulations promulgation.

TRACK I - PROBLEMS AND RECOMMENDATIONS
TABLE I

PROBLEM	RECOMMENDATION	STATUS
1. State Licensure Inspections The Division of Licensing and Certification of the Maryland Department of Health and Mental Hygiene (DHMH) and the Joint Commission on Accreditation of Hospitals (JCAH) both inspect acute general hospitals. This results in duplication and use of State resources which can be used to meet other needs.	Annual licensing inspections by the DHMH should be eliminated in hospitals holding accreditation from the JCAH.	X
2. Hospital Laboratory Inspections The Maryland State Laboratory Administration of the DHMH inspects acute general hospital laboratories. The College of American Pathologists also performs a similar inspection.	The State of Maryland should accept, for licensure purposes, inspections conducted by the College of American Pathologists.	X
3. Inpatient Psychiatric Licensure Inspection The Mental Hygiene Administration is statutorily assigned responsibility for inspecting inpatient psychiatric units in acute general hospitals. The Division of Licensing and Certification, at the time, also inspected the hospitals.	The Secretary of Health and Mental Hygiene should assign inpatient psychiatric unit inspections to the Division of Licensing and Certification from the Mental Hygiene Administration. (Reassigned to JCAH by HB 1621.)	X
4. Blood Bank Inspections The Maryland State Laboratory Administration of the DHMH inspects acute general hospital blood banks. The American Association of Blood Banks also inspects hospital blood banks.	American Association of Blood Banks inspections should be accepted by the Department of Health and Mental Hygiene.	X
5. Drug Control Inspections The Division of Licensing and Certification as well as the Division of Drug Control inspect acute general hospital pharmacies. In order to provide better comprehensive inspections, both in the pharmacies and at the nursing station drug storage areas, inspections for pharmaceuticals should be carried out solely by the Division of Drug Control which has the expertise in this area.	The Division of Licensing and Certification of the Department of Health and Mental Hygiene should assume responsibility for Occupational Safety and Health (OSHA) inspections from the Commissioner of Labor and Industry, Department of Licensing and Regulation. (Reassigned to DHMH, Regulatory Services)	X
7. Fire Safety Regulations Several instances were documented where there were differences of opinion between the State Fire Marshal and the JCAH in the subject areas of patient windows and door latching devices. These differences of opinion resulted in confusion in acute general hospitals as to whose recommendation to follow.	The State Fire Marshal should be given the responsibility of resolving inconsistencies in regulations pertaining to patient room windows and door latching devices. (Agreed to with JCAH).	X
8. Fire Safety Inspections The potential exists for differences of opinion between local fire authorities and the JCAH in life safety areas because inspections are not made at the same time.	To the extent possible, the State Fire Marshal and the Baltimore City Fire Department should coordinate their inspections with JCAH. JCAH should accept local recommendations when joint inspections are conducted.	X
9. Track I, Phase II Rules and regulations are promulgated with hard to interpret requirements both as to fiscal impact and data impact.	Department of Health and Mental Hygiene rules and regulations should require specific data impact statements.	X

X = Implemented

3.2 TRACK II Activities

3.2.1 Conceptual Approach

Early in its deliberations the Task Force decided that true streamlining of the regulatory process would entail limiting regulatory oversight to one agency. After a preliminary investigation the Task Force selected three areas and decided to: 1) investigate the extent of duplication and 2) explore the feasibility of limiting oversight to one agency. The three areas included: 1) quality of care, 2) utilization review, 3) equal access to care by minorities. In addition to studying each of these areas, the Task Force felt it was necessary to establish contacts at the state and federal level to develop acceptance of its conceptual approach; that is, to limit regulatory oversight to one agency. Prior to conducting investigations in the three study areas selected, the Task Force concentrated on establishing contacts at the state and federal level. These activities are described in the following section.

The primary objective of these activities was to establish acceptance of the concept that only one agency should have regulatory oversight for a given area within a health care institution. Members of the Task Force believed that it was essential for officials at both the state and federal level to "buy into" this approach. It was also felt that contact must be made with officials at JCAH in order to ensure their ultimate acceptance of the recommendations put forth by the Task Force. In line with this, members of the Task Force met with state, federal, and JCAH officials. Each Director and Chief of the Department of Health and Mental Hygiene in the regulatory area was also interviewed. Task Force members also met with officials from the Federal Office of Budget Management and the Department of Health and Human Services. Officials from the Health Care Financing Administration also met with representatives of the Task Force on Hospital Regulations. Representatives from the Health Care Financing Administration as well as the JCAH were extremely enthusiastic about the approach taken by the Task Force. Members of the Task Force found that the solution being pursued by the Task Force was consistent with the Reagan Administration's desire to reduce regulatory duplication and overlap.

While ultimately it was not necessary to seek federal support for individual Task Force recommendations, the Task Force felt that establishment of contacts and general support at the federal level was an important aspect of the activities of the Task Force. Most important, however, were the contacts and support established with the officials of the State and JCAH. These contacts paved the way for the eventual support and adoption of Track I recommendations.

3.3 Findings and Recommendations

As Track I activities neared completion, the Task Force began to focus its efforts on assessing the feasibility of implementing its long term strategy to reduce regulatory duplication.

Subcommittees were formed to investigate those areas where more than one agency had historically been assigned regulatory oversight: 1) quality of care, 2) utilization review, and 3) equal access to care by minorities. Findings and recommendations are presented in the following section. Full committee reports can be found in Appendix C.

3.3.1 Quality of Care

The original issues identified in this area concerned the role of Professional Standards Review Organizations and other organizations involved with monitoring quality of care. For instance, JCAH required hospital participation in quality assurance studies, PSRO's required quality assurance studies, and hospitals do quality assurance as a by-product of their overall liability control system.

Upon investigation, the Task Force did not find evidence of true regulatory duplication in the monitoring of quality of care. The Task Force found that there are federal, state and JCAH requirements prescribing hospital participation in quality assurance studies. The Task Force determined that JCAH requirements are already coordinated so that compliance with JCAH standards serves as compliance with federal and state standards.

Noting the lack of problems in duplication of regulations, it was decided that attention should be focused on what hospitals could do to improve the monitoring of quality within their institutions. An examination of the issue revealed the need for a systematic, objective program to evaluate the performance of physicians and other hospital professionals as part of a hospital's quality assurance system.

The Task Force concluded that the development of a systematic approach goes beyond its charge and mandate. However, the need for some hospital guidance is important. To this end, the Task Force recommends that physician renewal privileges be used in a systematic manner to monitor the quality of patient care.

The Task Force endorses the development of guidelines for such a system using the following data sources:

1. Health Services Cost Review Commission data including mortality, length of stay, cost effectiveness;
2. Malpractice Insurance data from insurance underwriters;
3. Medical and Chirurgical Faculty;
4. Commission on Medical Discipline data; and
5. Generic Screening profile data.

The Task Force supports the use of these data elements to form the basis of individual confidential physician profiles to be used by individual hospitals. Profiles would be reviewed by department chairpersons who, upon finding sub-optimal data, would arrange in-depth chart reviews and/or personal interviews. The author of the proposed approach, Arthur Kaufman, M.D., suggests that the results of the assessment would be an objective, reasoned recommendation to medical committees and boards of directors.

It is hoped that the guidelines developed by Dr. Kaufman will be used to:

1) Stimulate further study and development of the topic of physician privileging by hospitals and their medical staffs; and,
2) Assist hospitals in dealing with the issue through the use of the Task Force's guidelines.

- A regionalized review system has developed in Maryland with little statewide coordination of objectives, standards, and desired outcomes outside of Medicaid cost containment measures.

- The use of different standards by different payors creates duplicate systems with confusing signals as to desired practice of providers.

- Hospital and physician performance under review programs are not always tied to and coordinated with other aspects of hospital and physician behavior. For example, institutional UR systems are a component of the hospital risk management program but UR procedures must be linked to other aspects of hospital liability control systems. A good example of this is when physician performance is not tied to the hospital's credentialling and privileging process.

- The regulations governing existing UR systems tend to be cumbersome and need to be streamlined. Procedures need to be developed which accomplish the objectives of the system, but these procedures should also be timely and not result in unnecessary costs to institutions.

Rather than identify specific solutions to these problems, the Task Force decided to adopt a set of principles based upon its understanding of how various groups are currently addressing utilization review issues and its knowledge of those problems associated with previous utilization control systems. The Task Force recommends that the following principles be used as a guide to those seeking to develop utilization review systems as well as those seeking to solve problems associated with previous review systems.

- Utilization review systems for hospitals, physicians, and other health care professionals should be continued because they are important components of quality assurance and cost containment programs.

- Utilization review systems should not impose duplicative requirements on hospitals.

- To the extent possible, all payors should adopt comparable review systems. Any system, however, must permit flexibility in intensity, scope and innovation. Specific standards and requirements should be developed, and these should be clearly communicated to participating hospitals, physicians, and other health care providers.

- Utilization review system requirements throughout the State should be coordinated.

- Payors should establish criteria for delegation of UR functions. Hospitals must demonstrate performance at a level sufficient to warrant delegated status. A system should be developed which monitors utilization review activities conducted on a delegated basis.

- Payors and employers should establish clear objectives and methodologies for their UR programs.

- Employers should adopt and insurers should advocate use of benefit packages that include incentives for appropriate utilization of health care services by physicians and hospitals.

The Task Force believes that the potential exists for the proliferation of disparate utilization review systems through the State. Those involved in the development, implementation and operation of utilization review systems must take the responsibility for working to avoid the development of this scenario. Because the Task Force believes that the potential for duplication in the area of utilization review truly exists, it recommends that a joint study be undertaken by the Department of Health and Mental Hygiene, the Maryland Hospital Association, and the Medical and Chirugical Faculty. These organizations should undertake an in-depth look at the whole area of utilization review focusing particular attention on the problems faced by hospitals and the public and private payors. The Department, MHA, and Med-Chi should be instructed to work with payors and key parties in developing a set of recommendations designed to coordinate and integrate utilization review efforts throughout the State.

3.3.3 Equal Access

The final area investigated under Track II activities was that of the extent of regulatory duplication between local and federal agencies in the conduct of their federally mandated duties under Title VI of the Civil Rights Act of 1964 and Section 504 of the Rehabilitation Act of 1973. The basic question the Task Force sought to answer was, "Have these local and federal agencies duplicated their efforts in Maryland's acute general hospitals?"

During its investigation of this issue, the Task Force learned that the Maryland Commission on Human Relations and the Baltimore City Community Relations Commission have no mandated authority to monitor the two federal programs under consideration, and it was learned from the DHMH Assistant Attorney General that the Governor does not have the authority through Executive Order or other means to assign DHMH the powers invested in the Maryland Commission on Human Relations under Section 5560, Annotated Code of Maryland as it applies to the hospitals in question. Therefore, the Task Force narrowed its focus to the frequency with which the Title VI Office and the Office for Civil Rights duplicate the efforts of each other.

The Task Force found that there was limited civil rights activity in acute general hospitals conducted by the Office of Civil Rights. During the five year period ending December 31, 1981, this office carried on: (1) two compliance reviews, (2) thirty complaint investigations, (3) ten pre-grant reviews, and (4) thirty-five requests for statistical data. The Task Force decided that although the activities of this office did not significantly overlap the activities of the Department of Health and Mental Hygiene, efforts to assign these responsibilities to one agency, DHMH, should nonetheless be explored.

The Office on Civil Rights (OCR) has been approached, and although positive about the Task Force proposal, has not committed itself to delegating its Maryland hospital equal access activities to DHMH. The OCR has suggested that it is willing to collaborate on statistical data needs which can be gathered by the Title VI Compliance Office. In addition, it has been suggested that the two offices can conduct joint equal access reviews.

The Task Force recommends that DHMH enter into a collaborative arrangement for the purpose of establishing a statistical data base and conducting its inspections with OCR.

4.0 Cost Savings

Precise cost savings cannot be assigned to each of the recommendations proposed by the Task Force and implemented by the Department of Health and Mental Hygiene. It is estimated that approximately $115,000 in savings will be realized by DHMH through the elimination of the State's role in state licensure inspections. It is estimated that up to one to two million dollars may be saved annually by the Maryland hospital industry. Acute general hospital personnel will no longer have to meet and relate to the large number of inspections and surveyors who have visited them in the past.

The Department of Health and Mental Hygiene will be able to redeploy scarce resources to other unfunded areas. Personnel who have historically been assigned to Division of Licensing and Certification hospital survey teams will now be available to work in such areas as long term care, domiciliary care and medical test units.

5.0 Conclusion

The Task Force on Hospital Regulations did not attempt to address the question of whether or not hospital regulations are needed; that is, the Task Force recognized that some regulation is needed to protect the public and to resolve problems. What the Task Force set out to do was identify where the regulatory system had become fragmented, where regulations overlapped, and where efforts of regulatory agencies conflicted or were duplicative.

It was feared that with the extraordinary growth in the number and scope of hospital regulatory agencies, the regulatory system would be riddled with duplication and regulatory overlap. The Task Force was pleased that this was not the case. Where substantial duplication was found, the Task Force recommended, and the State accepted, proposals to eliminate the conflict and consolidate where possible. The area in which duplication of regulatory effort was most apparent, troublesome and costly was in the area of licensing and certification. As a result of the Task Force's recommendation, the annual licensing inspection by the Department of Health and Mental Hygiene was eliminated for hospitals that are accredited by the Joint Commission on Accreditation of Hospitals. This action has removed considerable overlap and duplication resulting in significant savings. Further, this recommendation has also been implemented without jeopardizing the protection of the public. A mechanism has been established to investigate and resolve complaints and non-JCAH accredited hospitals will continue to be surveyed by the State.

The acceptance of other changes by the American Association of Blood Banks, the College of American Pathologists, the DHMH Division of Drug Control, Title VI Equal Access Compliance Office, and the State Fire Marshal has also eliminated duplication by assigning a single entity with responsibility for surveillance and compliance.

The Task Force endorses the concept that regulatory oversight should not be fragmented among agencies. Recommendations in the areas of quality of care, utilization review and equal access serve to move the State closer to achieving such a system while continuing to maintain the highest possible standard of care in Maryland's health care institutions. The Task Force hopes that those Track II recommendations that require additional effort will be carried on by the appropriate parties.

6.0 APPENDIXES

APPENDIX A: EXHIBIT I - MEMBERS OF TASK FORCE

EXHIBIT II - AD HOC MEMBERS, CONSULTANTS, STAFF

EXHIBIT III - SUBCOMMITTEES AND MEMBERSHIP

EXHIBIT I

TASK FORCE ON HOSPITAL REGULATIONS: MEMBERSHIP

Maryland Hospital Association
Mr. David Christman, President
South Baltimore General Hospital

Ms. Sarajoan Norcross
Associate Administrator for Operations
Lutheran Hospital

Maryland Nurses Association
Ms. Marilyn McGrath, Director
Medical/Surgical Nursing
University Hospital

Medical and Chirurgical Faculty
Dr. John N. Diaconis
Professor of Radiology
University Hospital

Blue Cross/Blue Shield
Mr. Fred Gloth
Vice President and General Counsel
Blue Cross of Maryland, Inc.

Department of Health and Mental Hygiene
Dr. Harold A. Cohen, Executive Director
Health Services Cost Review Commission

Mr. Bertram Zimmerman, Administrator
Crownsville Hospital Center

General Public
Mr. Gordon H. Dalsemer, Chairman of Task Force
Chairman of the Board
Dalsemer, Catzen and Associates, Inc.

The Honorable Elmer Horsey
Mayor of Chestertown

Dr. Richard J. Martin
Retired Hospital Administrator

House Environmental Matters Committee
The Honorable Judith C. Toth
House of Delegates
Montgomery County

House Economic Matters Committee
The Honorable Patricia R. Sher
House of Delegates
Montgomery County

Senate Economic Affairs Committee
The Honorable Edward P. Thomas
Senate of Maryland
Washington and Frederick Counties

Senate Finance Committee
Vacant

PAST MEMBERSHIP

Maryland Hospital Association
Mr. Womack Rucker, formerly
General Vice President
Washington Adventist Hospital

Mr. Robb Ruyle, formerly Director
Memorial Hospital of Cumberland

Ms. Diane Gustafson, formerly
Assistant Director
Baltimore City Hospitals

Mr. William Jews, President
Lutheran Hospital

Maryland Nurses Association
Ms. Elizabeth O'Connell
Vice President for Nursing & Patient Care
Montgomery General Hospital

Department of Health and Mental Hygiene
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Spring Grove Hospital Center

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Ms. Kathleen Francis
Retired School Teacher

Senate Finance Committee
Former State Senator Aris T. Allen

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APPENDIX B

STATUTES CONCERNING THE ADOPTION OF REGULATIONS

STATUTES CONCERNING THE ADOPTION OF REGULATIONS

Article 41, §9 Adoption of Rules and Regulations

Administrative Procedure Act (Article 41, §§244-256A):

- Article 41, §245 Adoption of rules.
- Article 41, §246 Compliance with §9 and State Documents Law.
- Article 41, §247 Publication, compiling and indexing of rules or regulations.
- Article 41, §248 Petition for adoption of rules.
- Article 41, §249 Declaratory judgment on validity of rules; severability of rule provisions.
- Article 41, §250 Petition for declaratory rulings by agencies.

State Documents Law (Article 41, §§256B-256T):

- Article 41, §256D Documents to be filed with the Division of State Documents.
- Article 41, §256H Material not to be published.
- Article 41, §256M Official text of documents.

Joint Standing Committee on Administrative, Executive and Legislative Review:

- Article 40, §40A(g) Emergency measures.

Governor's memorandum of October 18, 1979.

Department of Health and Mental Hygiene:

- Article 41, §206 Creation and composition of Department; Secretary of Health and Mental Hygiene.
- Article 41, §206(k) Rules and regulations.
- Article 43, §1F Powers and duties of the Secretary of Health and Mental Hygiene (contains some regulatory authority)
- COMAR 10.01.01 Procedures for Promulgation and Adoption of Regulations
- Procedure D.H.M.H.-1 Procedure Governing the Adoption of or Amendments to Regulations Affecting the Public.

Division of State Documents closing dates and publication schedule.

APPENDIX C

SUBCOMMITTEE REPORTS

QUALITY OF CARE
SUBCOMMITTEE REPORT

Report to the Governor's Task Force on Hospital Regulations
From the Track II Subcommittee on Quality Assurance

The Quality Assurance Subcommittee could find no evidence of true regulatory duplication in its area of study. There are federal, state and Joint Commission on Accreditation of Hospitals requirements prescribing hospital participation in quality assurance studies. These requirements are reasonably coordinated so that compliance with JCAH standards serves as compliance with federal and state standards.

Despite hospital compliance with existing quality assurance standards, the number of malpractice suits is increasing. Suits have also expanded to include the entire medical staff and boards of directors individually and collectively. (See Corleto vs. Shore Memorial Hospital and the Misracordia Case.) These cases focus on the failure of hospitals to perform privileging and reprivileging functions in a systematic, objective manner, and then monitor those privileges granted.

Each medical staff is delegated the responsibility of evaluating the performance of its professional members and making recommendations to the board of directors regarding physician appointments and the renewal of privileges. Very few hospitals have a systematic, objective approach to this task. Such an approach is needed and should be applied uniformly throughout Maryland hospitals.

The subcommittee concluded that the development of a systematic approach goes beyond its charge and mandate. However, the need for some hospital guidance on this matter is important. Consequently, the subcommittee prepared the following guidelines. The document has two essential purposes:

1) To stimulate further study and development on the topic of physician privileging by hospitals and their medical staffs; and,

2) To assist hospitals in immediately dealing with the issue through the use of the subcommittee's guidelines.

To this end, it is proposed data elements serve as the basis of individual physician profiles at each hospital.

1. Maryland Health Services Cost Review Commission Data

   a. Mortality Rates
   b. Utilization/Length of Stay
   c. Cost Effectiveness

2. Malpractice Insurance Data from Insurance Underwriters

3. Data from Medical and Chirurgical Faculty of Maryland

4. Data from the Maryland Commission on Medical Discipline

5. Generic Screening Criteria Profile Data

The data elements specified above could be incorporated into an annual confidential profile matrix on each medical staff member. This profile would be reviewed by the department chairperson, who, upon finding suboptimal data, would arrange an in-depth chart review and/or personal interview. The result would be an objective, reasoned recommendation to the Medical Executive Committee and Board of Trustees.

The data elements are not meant to stand alone. They are merely red flags that serve to encourage further investigation and clarification before a definitive recommendation can be made. Without such data, however, the task is entirely subjective or anecdotal. With such data, the capricious application of criteria is avoided.

Maryland Health Services Cost Review Commission (HSCRC) Data

Each acute hospital in the State of Maryland is required to compile and report specific information concerning every inpatient admission to its facility. This data is sent to the HSCRC where it is assembled into profiles related to costs of care by the hospital as a whole, by department, by physician, by diagnosis, by diagnostic-related groups, etc. The resulting analysis can be used by the medical staff to create physician profiles of mortality rates, length of stay, and cost effectiveness. This does not mean that the physician with the highest mortality rate or the greatest length of stay is practicing suboptimally. In fact, such aberrant data could be part of a profile reflecting the most competent neurosurgeon, managing the most challenging patients. Because of such possibilities, non-normative profile elements must be tempered by the judgment of the department chairperson, the Executive Committee of the Medical Staff and the Board of Trustees at the time of privilege renewal.

Malpractice Insurance Data

Most hospitals require physicians to report any adjudicated malpractice claims in which the plaintiff has been successful. A more complete and perhaps a more useful view would be a listing of all claims for the previous five years. While the issue of guilt or innocence may be important, of equal relevance is the concern for potential hospital liability risk. The physician who is frequently sued may be a poor performer, or may have an abrasive personality, or may be in an extremely high risk area of medicine. The latter determinations should be tasks of the department chairperson.

Maryland Commission on Medical Disciplina Data

The Health Occupations Section of the Maryland Annotated Code requires that all significant changes in privilege status that are acted on by the Hospital Board of Trustees be reported to the Commission on Medical Discipline. This is also the repository for complaints by health consumers and criminal charges against health providers. Such information is rarely requested by the department chairperson at the time of privileging decisions. This information may not alter the privilege renewal, but it would provide an additional dimension in the recommendation process.

Generic Screening Profile Data

The generic screening concept was developed through a joint effort of the California Medical Association/California Hospital Association and InterQual. These criteria were designed to cull adverse patient outcomes (APO) based on the closed claims files of the National Association of Insurance Commissioners. Originally, these generic screening criteria were used to determine if a no-fault form of malpractice insurance was feasible. However, over time, this data collection method has been found to serve as a powerful risk assessment tool for hospitals.

If acute care hospitals would adopt generic screening criteria, department chairpersons could begin to appreciate overall departmental risks as well as the hazards presented by individual physicians. Again, this data should merely serve as a red flag indicating that further review and investigation is necessary. It may also serve to guide the department/hospital in developing safer policies and procedures.

Summary

The anxiety being experienced by medical staffs and acute hospitals at the time of privilege renewal has been magnified by recent case law. These guidelines will assist hospitals to modify the privileges of a suboptimal physician to protect the patient population and reduce the possibility of a malpractice action. By arming the Medical Staff and Board of Trustees with solid, objective documentation, the process becomes more manageable. While these guidelines will need to be further developed and expanded, they will serve as a starting point for hospitals and the physician community.

Appendix

Tentative Outline of Implementation Steps

1. Devise a unified privileging format which would:
   a. allow the hospital to obtain the necessary data through a physician release of information statement;
   b. ask the appropriate questions of each medical staff member; and
   c. insure confidentiality of such acquired information. The wording for this privilege form should be carefully worked out in consultation with a hospital attorney.

2. Establish a timetable for the phasing in of these guidelines:
   a. Educational component of Maryland Hospital Association Education Institute
   b. Experimental use by hospitals
   c. Incorporation into JCAH survey

3. Solicit support of the various medical/hospital/insurance bodies within the State. This support must also be gained gradually and in writing.
   a. Educational presentation to invited components*
   b. Written support for experiemental period
   c. Analysis of effectiveness/impact
   d. Review and modification of program
   e. Incorporation into JCAH survey

*The invited components should include but not be limited to Med Chi, MHA, Med Mutual, USF&G, and DHMH.

UTILIZATION REVIEW
SUBCOMMITTEE REPORT

INTRODUCTION

The Governor's Task Force on Hospital Regulations charged the Utilization Review Subcommittee with the responsibility to investigate the extent to which there was regulatory overlap and duplication in the area of utilization review (UR). In addition, the Subcommittee was to recommend what action should be taken as a result of its findings. What follows is a summary, background statement, and several principles which are intended to address the issue at hand.

BACKGROUND

One could most accurately define the present status of utilization review as extremely "fluid," that is, Maryland is experiencing significant changes as utilization review functions (in hospitals and elsewhere) evolve from the old to the new. The rapid rate at which these changes are now occurring is indicative of the pressures that are being exerted by the government, industry, insurers, and the health care community.

The true extent to which overlap and duplication exist within the utilization review process is difficult to document at this time. It is the belief of the Subcommittee that its best contribution would be to focus on the broader, conceptual aspects of the problem rather than define the essential elements of a utilization review system. If all parties would recognize and be cognizant of the principles that are identified in this report, duplicative and/or unnecessary efforts in utilization review might be avoided.

A few comments on the Maryland environment are appropriate. Compared to how it was originally conceived by the Federal government, the role and functions of Professional Services Review Organizations (PSROs) are changing. Examples of this include: defunding of several Maryland PSROs as this pertains to Medicare review; termination of operations of two local PSROs; State Medicaid initiatives to contract individually with the various utilization control agents -- the successors to PSROs; and Congressional and federal Department of Health and Human Services discussions to eliminate PSROs altogether.

This changing environment in the area of utilization review has also coincided with severe pressures to contain unprecedented increases in Medicaid inpatient utilization. As a result, the Medicaid Program made changes in its UR procedures and restricted benefits. Thus, the Subcommittee found that utilization increases and attendant costs had emerged as the priority issue, and payors and employers had intensified their efforts to seek a solution.

As the Subcommittee explored the issue of utilization review, it became apparent that the need for a utilization review system in hospitals is well established. Utilization review is recognized as an important component of the overall institutional quality assurance system which also includes risk management and liability control. The primary concern voiced by hospitals was the extent to which specific, unique obligations would be externally imposed on the individual hospitals. This issue concerns the extent to which Medicaid, other payors, and employers may impose requirements on the hospital to do or be subject to reviews which result in duplication and overlap in the hospital's UR system. There is considerable concern on the part of hospitals that a myopic view will be taken which focuses only on individual payor needs and not on what individual actions will do to the internal operations of a hospital. Payors and employers have a somewhat different perspective. They are concerned about the need to establish a system which assures that the care it pays for is medically necessary, appropriate, and delivered in the most economical setting.

In Subcommittee discussions, it also became apparent that there is more to the issue than the potential duplication and overlap posed by different UR approaches. The Subcommittee recognized that there may be a direct relationship between benefit packages and the utilization of hospital services. The experience of the Medicaid Program in controlling utilization review procedures and benefit restrictions demonstrates that a public agency can impact on the use of hospital and physician services. The Subcommittee felt that private payors must study the Medicaid experience and determine if the approach used is appropriate for use in meeting their respective goals. The Subcommittee, however, recognized that until the issue of health benefits is addressed by both employers and payors, UR as a tool for controlling utilization will not reach its full potential.

The Subcommittee also learned that as pressures mounted throughout the State to reduce utilization, the demise of the federally supported system for Medicaid recipients threatened to create a vacuum. Several initiatives were underway as a result. These are described below.

The Medicaid Program decided that PSRO review under Federal mandate, which relied heavily on delegation and focused review, was ineffective. Beginning in January, 1981, therefore, the State prevailed on the Federal government to approve PSRO preadmission review of a substantial number of procedures which might be performed as outpatient and PSRO approval of more than one preoperative day. As the State implemented a 20-day per spell of illness inpatient cap at the same time, the PSROs were authorized to certify second spells of illness when such necessitated a hospital stay in excess of 20 days. The State followed this by contracting privately with each PSRO for admission review of all Medicaid patients, starting with fully State funded patients in February, 1981, and adding all Federal Medicaid patients in July, 1981. Consequently, when the PSROs began losing Federal funding to perform Medicaid review - one in September, 1981, one in November, 1981, and two in January, 1982 - the State review program, using the PSROs as Utilization Control Agents, was already fully operational; and there was no transition period.

Private payors and employer groups have also begun to undertake independent initiatives to address the problem of utilization control. Blue Cross of Maryland has been investigating, on its own and as the representative of several major organizations, the best approach for controlling utilization. The Health Care Coalition, which represents providers, major employers, regulators, and private and commercial payors, has been designing a quality assurance program to do more intensive retrospective review. Major employers have independently contacted hospitals regarding the need for more intensive utilization review controls. Representatives of self-insured companies have also contacted the Maryland Hospital Association (MHA), PSROs, and individual hospitals seeking solutions to increasing utilization of health care benefits. The Subcommittee met with a number of these groups to review their concerns.

The Subcommittee found that hospitals and physicians are concerned about the development of multiple layers of review systems. Given the number of initiatives already underway, the Subcommittee agreed that the potential existed for the development of costly and duplicative review systems. It appears that the health care community may be faced with a problem unless some type of coordination of UR efforts is achieved.

PROBLEMS

The potential lack of coordination among payors and employers in the development of UR programs was only one of the problems identified by the Subcommittee. Throughout its deliberations, the Subcommittee also identified several other problem areas that are associated with existing review systems. These problems include:

- With the exception of the State Medicaid Program, payors have not clearly defined the methodologies needed to achieve their utilization review objectives.
- A regionalized review system has developed in Maryland with little statewide coordination of objectives, standards, and desired outcomes outside of Medicaid cost containment measures.
- The use of different standards by different payors creates duplicate systems with confusing signals as to desired practice of providers.
- Hospital and physician performance under review programs are not always tied to and coordinated with other aspects of hospital and physician behavior. For example, institutional UR systems are a component of the hospital risk management program but UR procedures must be linked to other aspects of hospital liability control systems. A good example of this is when physician performance is not tied to the hospital's credentialling and privileging process.
- The regulations governing existing UR systems tend to be cumbersome and need to be streamlined. Procedures need to be developed which accomplish the objectives of the system, but these procedures should also be timely and not result in unnecessary costs to institutions.

PRINCIPLES

The Subcommittee has developed a set of principles based upon its understanding of how various groups are currently addressing utilization review issues and its knowledge of those problems associated with previous utilization control systems. The Subcommittee recommends that these principles be used as a guide to those seeking to develop utilization review systems as well as those seeking to solve problems associated with previous review systems.

The Subcommittee recommends that the Governor's Task Force on Hospital Regulations endorse the following principles:

1. Utilization review systems for hospitals, physicians, and other health care professionals should be continued because they are important components of quality assurance and cost containment programs.
2. Utilization review systems should not impose duplicative requirements on hospitals.
3. To the extent possible, all payors should adopt comparable review systems. Any system, however, must permit flexibility in intensity, scope, and innovation. Specific standards and requirements should be developed, and these should be clearly communicated to participating hospitals, physicians, and other health care providers.

4. Utilization review system requirements throughout the State should be coordinated.

5. Payors should establish criteria for delegation of UR functions. Hospitals must demonstrate performance at a level sufficient to warrant delegated status. A system should be developed which monitors utilization review activities conducted on a delegated basis.

6. Payors and employers should establish clear objectives and methodologies for their UR programs.

7. Employers should adopt and insurors should advocate use of benefit packages that include incentives for appropriate utilization of health care services by physicians and hospitals.

The rationale for each of these principles is discussed in the remainder of this paper.

The first principle recommended is basically an endorsement of the continuation of UR systems for hospitals and physicians. There was little debate over this issue. The Subcommittee recognizes, however, that utilization review activites are just one facet of utilization control. An effective combination of UR procedures, benefit alternatives, and provider performance incentives is necessary to reduce utilization and assure quality of care.

One of the primary concerns of hospitals is that varied UR approaches will be adopted by different payors. As a result, hospitals will be faced with implementing many systems, each with different standards and expectations. Lack of uniformity or comparability between requirements at the institutional level will result in burdensome and costly systems.

The Subcommittee recommends that all payors adopt comparable utilization review systems in order to avoid, to the extent possible, duplication at the institutional level. It is further recommended that these systems include specific standards and requirements that are clearly communicated to hospitals, physicians, and other health care providers.

Although a uniform statewide system would be optimal from the perspective of ease of implementation, the Subcommittee recognizes that this may not be possible, that is, it may be necessary for some payors to impose a more intensive approach to controlling utilization to meet group requirements or demands. Other payors may require a less intensive approach to certain groups. A reasonable and realistic balance must be reached. In order to achieve this balance, the Subcommittee recommends that flexibility be built into the development of the review systems. It is imperative, however, that every effort be made to avoid the development of duplicative systems.

The third principle recommended by the Subcommittee is that, to the extent possible, utilization review activities be coordinated throughout the State. A coordinating mechanism is needed to work with participating payors to develop comparable standards and, to the extent possible, one set of rules and requirements. The Medical and Chirurgical Faculty, for example, is currently exploring ways in which their organization might serve to coordinate UR activities. It is recommended that all payors and employer groups work to coordinate their efforts in order to minimize the potential overlap and duplicaltion that may be created at the regional and institutional levels.

The Subcommittee identified several key advantages for establishing a coordinating mechanism for UR activites. The first has already been mentioned; that is, a coordinating mechanism will minimize the amount of duplication at the institutional level. A coordinated approach will also foster the development of a core set of basic UR standards and requirements. Institutions and physicians can be better monitored if a coordinated approach is used. Finally, payors can work together to address issues that cut across the State, to assess the efficacy of current UR approaches, and to develop new UR approaches.

The Subcommittee recommends that payors should establish criteria for the delegation of UR functions. Payors should also involve hospitals in the development of these criteria. The Subcommittee recognizes that there is strong sentiment on the part of hospitals and physicians that they are best qualified to conduct UR activities in their own institutions. The Medicaid Program, however, has serious doubts about the contention that UR is best accomplished on a delegated status. The Subcommittee believes that payors should establish criteria for delegation and that hospitals should have the opportunity to demonstrate they qualify for delegated status. Hospitals on delegated status should also be monitored through a data system. When a hospital is found out of compliance with established standards and rules, the institution's delegated status should be subject to withdrawal. The details of such a monitoring system and the conditions for removing an institution's delegated status should be established in a coordinated fashion by payors, employers, and hospitals.

It is extremely difficult, if not impossible, to determine how effective a UR program is if objectives and methodologies for such programs are not established beforehand. To date, few employers and payors, with the exception of Medicaid, have clearly established objectives and methodologies. The Subcommittee recommends that payors and employers establish objectives and methodologies for their UR programs and establish a system to monitor progress in meeting objectives. The benefits and costs of UR systems can only be truly weighed if objectives and methodologies have been established and evaluated.

The members of the Subcommittee agreed that business, labor, and other groups should be made more sensitive to their influence on employee utilization of hospital services. This influence is manifested through various incentives and disincentives found in employee benefit packages. The Subcommittee agreed that in the past too much has been expected of utilization review systems, and not enough attention has been paid to the influence of incentives contained in benefits and services covered by insurances. The Subcommittee believes that the effectiveness of utilization review systems is closely linked to private and public insurance packages.

The Subcommittee found that various changes to benefit packages which would alter existing incentives and disincentives are already being considered and/or implemented at the national level as well as within Maryland. These approaches include the following:

- Specifying procedures which must be done on an outpatient basis;
- Requiring authorization if more than one preoperative day is necessary;
- Increasing cost sharing;
- Expanding benefits to cover less intensive levels of care, such as home care; and
- Providing employees with an approved list of physicians and limiting reimbursement to these physicians.

The Subcommittee encourages those groups working to coordinate and resolve problems with utilization review systems to study the influence of incentives and disincentives on utilization of hospital services. Prior to endorsing the adoption of any proposals designed to change utilization of services, the Subcommittee believes that the issue should be more thoroughly studied. It is recommended that business and industry, as well as payors, should work together to develop changes in benefit packages that will help reduce unnecessary utilization.

The Subcommittee did not develop a principle to address the problem of the cost of UR systems to providers. However, a basic tenet of the Task Force on Hospital Regulations is the avoidance of duplicative and/or cumbersome regulations that create unnecessary costs to institutions. Those responsible for the development of regulations concerning UR systems should be urged to design regulations that promote a streamlined and timely process that avoids unnecessary costs to providers.

CONCLUSION

The Subcommittee believes its efforts should be of assistance to those payors and employers seeking a more effective process for monitoring the utilization of health services. Hospitals, and physicians as well, should have the heightened concerns of those wishing to reduce unnecessary utilization. The efforts of the Subcommittee, however, only graze the surface of a potential problem that is expected to significantly grow over the coming years. That is, the potential exists for the proliferation of disparate utilization review systems throughout the State. Those involved in the development, implementation and operation of utilization review systems must take the responsibility for working to avoid the development of this scenario.

This report identifies the parameters of the problem and puts forth a set of principles designed to resolve these problems. The Subcommittee believes, however, that the problems identified in the report require further study and investigation. An in-depth study of this nature is beyond the mandate of the Subcommittee, as well as that of the Governor's Task Force on Hospital Regulatons. The Subcommittee urges the Task Force to recommend that a joint study be undertaken by the Department of Health and Mental Hygiene, the Maryland Hospital Association, and the Medical and Chirurgical Faculty. These organizations should undertake an indepth look at the whole area of utilization review, focusing particular attention on the problems faced by both hospitals and the public and private payors. The Department, MHA, and Med-Chi should be instructed to work with payors and key parties in developing a set of recommendatons designed to coordinate and integrate utilization review efforts throughout the State.

EQUAL ACCESS
SUBCOMMITTEE REPORT

GOVERNOR'S TASK FORCE ON HOSPITAL REGULATIONS
SUBCOMMITTEE ON EQUAL ACCESS

Final Report

This subcommittee had as its primary charge the assessment of the extent to which local and federal agencies in the conduct of their federally mandated duties under Title VI of the Civil Rights Act of 1964 and Section 504 of the Rehabilitation Act of 1973 have duplicated their efforts in Maryland acute general hospitals.

The central agencies scrutizined during our deliberations have been the Title VI Compliance Office (Department of Health and Mental Hygiene), the Office for Civil Rights (OCR), (Department of Health and Human Services), the Maryland Commission on Human Relations and the Baltimore City Community Relations Commission. The two latter agencies have no mandated authority to monitor the two federal programs under consideration, and it was learned from the DHMH Assistant Attorney General that the Governor does not have the authority through Executive Order or other means to assign DHMH the powers invested in the Maryland Commission on Human Relations under Section 5560, Annotated Code of Maryland as it applies to the hospitals in question. Therefore, the focus of this subcommittee was narrowed to the frequency with which the Title VI Office and the Office for Civil Rights duplicate the efforts of each other.

The subcommittee learned that the Office for Civil Rights, during the five year period ending December 31, 1981, carried on the following civil rights activities in acute general hospitals: (1) two compliance reviews, (2) thirty complaint investigations, (3) ten pre-grant reviews, and (4) thirty-five requests for statistical data. The subcommittee felt that this activity hardly represented onerous duplication, but sought to explore with the Office for Civil Rights the feasibility of its delegating all of its Maryland hospital equal access activities to the Department of Health and Mental Hygiene.

Subsequent subcommittee meetings with OCR personnel yielded generally positive responses to our proposal, but as yet no approval commitment. The Office for Civil Rights is evaluating the mechanism to be employed in its Block Grant system whereby state governors have sixty days to investigate and resolve allegations of non-compliance. OCR is considering designating seven states (Maryland is one of the states being considered) as subjects for a pilot program for this issue. Until the pilot program is launched, OCR will not make a determination on the Department's request to explore the feasibility of delegation of OCR responsibilities.

However, the Acting Director of OCR, Region III, Mrs. Yvonne Brown, has suggested that her office and the Title VI Compliance Office can collaborate on statistical data needs which can be gathered by the Title VI Compliance Office. In addition, Mrs. Brown suggested that the two offices can conduct joint equal access reviews.

Pursuant to the meeting held on July 13, 1982, between subcommittee members and representatives from both the regional and headquarters staffs of the Office for Civil Rights, Mr. Leonard Yorke, Director, Title VI Compliance Office, DHMH, attempted on several occasions to get in writing from Region III a confirmation of the suggestions made by the Region III Acting Regional Director at the July 13, 1982 meeting.

On August 25, 1982, Mrs. Brown talked with Mr. Leonard Yorke saying that her office will collaborate with the Title VI Office on both the establishment of a statistical data base and the conduct of on-site reviews of our acute general hospitals.